AMENDMENTS TO THE FIGURES

Enclosed are two sheets of replacement figures under 37 CFR § 1.121. Figures 2B and 3 have been amended.

Figure 2B has been amended to delete reference number 55. There is no reference number 55 in the specification and Applicants' addition of reference number 55 in Figure 2B was a clear error.

Similarly, Figure 3 is being amended to delete reference number 104 as the specification as originally filed does not have reference number 104.

REMARKS

Claims 1-10, 13-19, and 21-45 are pending in the application. The pending claims have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.[1] The Examiner claims that the term "implanted on a molecular level" was not included in the specification as filed.[2] The Examiner has also objected to this phrase under 35 U.S.C. § 132(a), which prohibits Applicants from introducing new matter into the invention disclosure that is not supported by the original application after the filing date.[3]

As the Examiner is well aware, when changes are made to the claims of the application, a § 132 new matter rejection is not appropriate.[4] Rather, lack of written description under § 112 is the appropriate basis for rejection when, as here, amendments have been made to the claims and not to the specification.[5] Regardless, courts faced with improper § 132 rejections, like in the instant case, have treated the rejection as though it was made under § 112.[6] Therefore, the Applicants analysis is the same regardless of the basis of rejection and will be treated as such in the response below.

"**In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in *haec verba* support for the claimed subject matter at issue**."[7] The Federal Circuit has consistently held that a claim limitation added by amendment is properly described in the original specification **so long as "one skilled in the art, reading the original disclosure, [can] immediately discern the limitation at issue in the claims**."[8] One Federal Circuit case dealt with a patent directed to a method for making a custom dental impression tray.[9] The lower court held

---

[1] Office Action (June 9, 2006).
[2] *Id.*
[3] *Id.*; 35 U.S.C. § 132 (West 2001).
[4] 2 Irah H. Donner, *Patent Prosecution: Law, Practice, and Procedure* 1436 (4th ed. 2005).
[5] *Id.* ("proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is Section 112, first paragraph, not Section 132.")
[6] *In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981).
[7] *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed.Cir. 2000).
[8] *Id. See also Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir.1998) ("in order for a disclosure to be inherent, however, the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure.")
[9] *All Dental Prodx LLC v. Advantage Dental Prods.*, 309 F.3d 774, 776 (Fed. Cir. 2002).

the patent invalid under § 112 for containing the phrase "original unidentified mass," which was introduced into the claims during prosecution to overcome prior art, but was not defined or described in the specification.[10] On appeal, the patent owner argued that while the phrase did not literally appear in the specification, one skilled in the art would recognize and know how to practice the claimed invention using "an original unidentified mass" upon reading the specification.[11] The Court recognized that the disclosed invention involved heating a mass of thermoplastic material that lacks an identifiable form.[12] It noted that the invention was described in the specification, although not "in haec verba."[13] It also reasoned that it was clear what the invention was not, since the specification did not describe an original material as having an identifiable form or shape.[14] Therefore, it held that the specification described the claimed invention within the meaning of § 112.[15]

The claims currently under examination are no different than the Federal Circuit case described above. **The issue is not whether the Applicants used *haec verba* the term "molecular level" in the specification as is erroneously contended by the Examiner, but whether one skilled in the art, reading the original disclosure, would immediately discern that the implantation is "on a molecular level**." Applicants submit that one skilled in the art, or one with even basic understanding of ion or plasma deposition, would understand that nitrogen is implanted at a molecular or atomic level if the description of paragraph 16 as well as table 1 on page 6 of the specification is followed. Similarly, one skilled in the art would, without any effort, acknowledge that titanium is deposited on an molecular or atomic level by the description of paragraph 18. For further support and plasma deposition parameters, the Examiner is respectfully directed to pages 7, 8 and 9 of the specification.

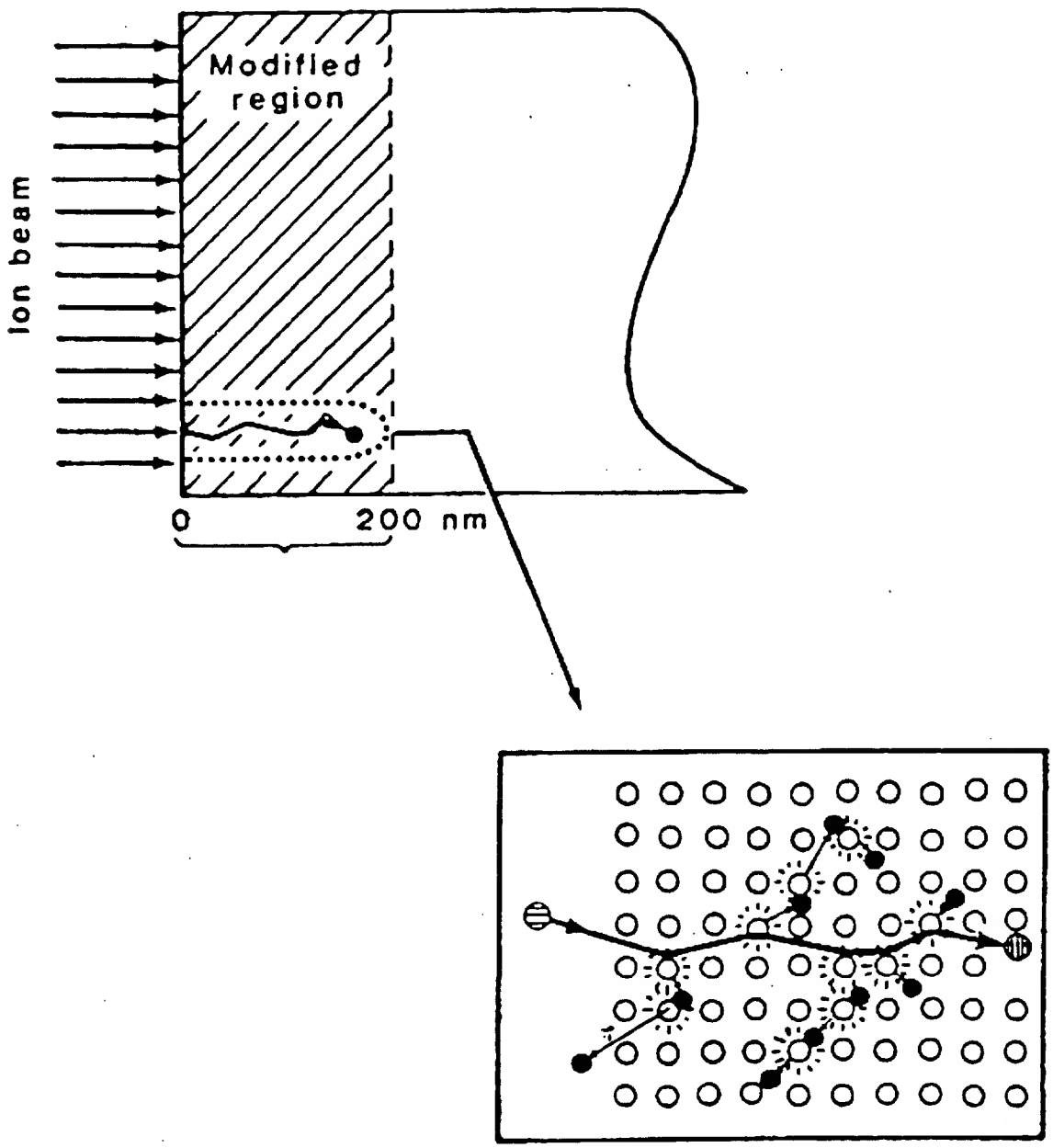
It should be noted that the claims have been amended to include both molecular and atomic sized implantation. This is to further clarify the end result of the deposition technique that is disclosed in the specification. As remarked in the office

[10] *Id.* at 777.
[11] *Id.* at 778.
[12] *Id.* at 779.
[13] *Id.*
[14] *Id.*
[15] *Id.*

action response of August 16, 2005, "Applicant uses the phrase 'on a molecular level' to indicate that the compounds being implanted or the compounds after implantation are atomic or molecular sized." **Simply put, following the recipe of the specification, one skilled in the art would immediately and easily recognize that the material is being deposited on an atomic or molecular level**.

Should the Examiner's technical background be outside the scope of present invention, as may be evident by the rejection that has been made by the Examiner, Applicants respectfully submit the following to try to explain ion implantation technology to the Examiner:

Applicants respectfully refer the Examiner to the ASM Handbook, Desk Edition. The ASM Handbook defines ion implantation as "the bombardment of a solid material with medium-to-high-energy ionized atoms and offers the ability to alloy virtually any elemental species into the near-surface region of any substrate. The advantage of such a process is that it produces improved surface properties without the limitations of dimensional changes or delamination found in conventional coatings. During implantation, ions come to rest beneath the surface in less than 10 to 12 s, producing a very fast quench rate and allowing the development of nonequilibrium surface alloys or compounds. Disadvantages of the process include shallow penetration depths (on the order of a few hundred angstroms) and relatively high capital and operating costs." The following figure (from ASM Handbook 5, Surface Engineering, Fundamentals of the Ion Implantation Process) illustrates ion implantation as described in the specification and its end result:



The figure shows a schematic view of the path **of individual atoms or molecules as they lose energy in a material, thereby forming a shallow surface-modified region**. **As indicated in the figure, the atoms or molecules do not travel in a straight path to the resting place, due to collisions with the target atoms. Target atoms are displaced from their lattice sites with sufficient energy that they can themselves displace additional target atoms, resulting in a collision cascade**.

Finally, enclosed is Dr. Kramer-Brown's declaration, who is one of ordinary skill in the medical device material art. **As stated in the declaration, Dr. Kramer would**

immediately and easily discern that the specification teaches implantation on a molecular or atomic level.

In sum, Applicants have provided more than an ample description for molecular and atomic level deposition. Applicants have gone as far as disclosing the process parameters involved in making such depositions, including gas flow rate, volume of the chamber, pressure, FR power and frequency required, and bias voltage used. The Applicants have provided a detail "cook book" recipe for one skilled in the art to practice the present invention. Applicants respectfully submit that such a disclosure is vastly in excess of what is needed to fulfill the requirement of 112, first paragraph.

Removal of the rejections and allowance of the claims is kindly requested. Should the Examiner maintain her position of contradicting the ruling of the Federal Circuit precedents, Applicants respectfully reserve the right to appeal this rejection following the next action.

Respectfully submitted,

Date: October 13, 2006

49,010 for

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0345
aaugustus@ssd.com

Cameron Kerrigan
Attorney for Applicants
Reg. No. 44,826

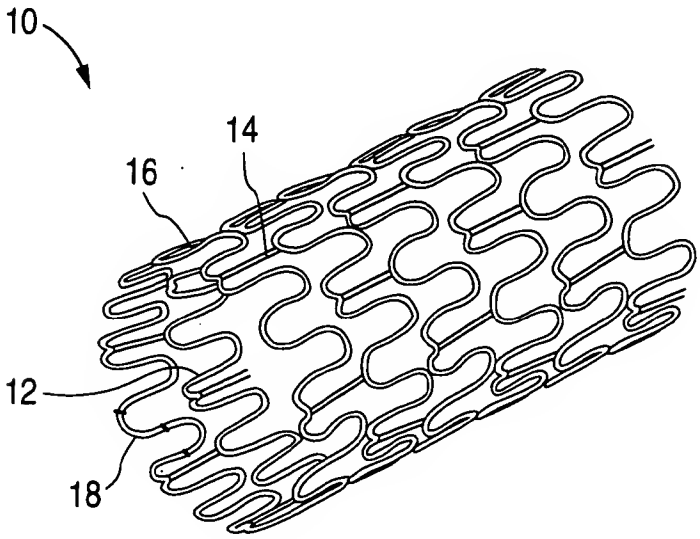


Figure 1

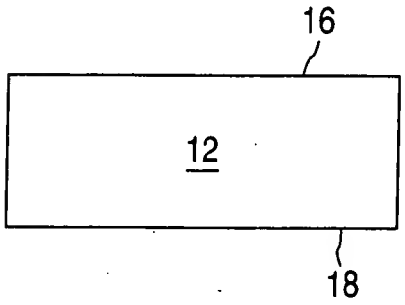


Figure 2A

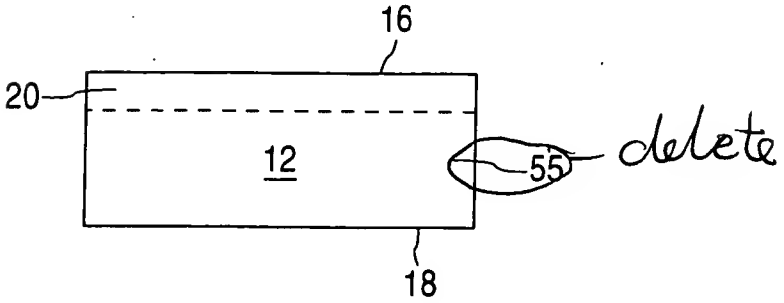


Figure 2B

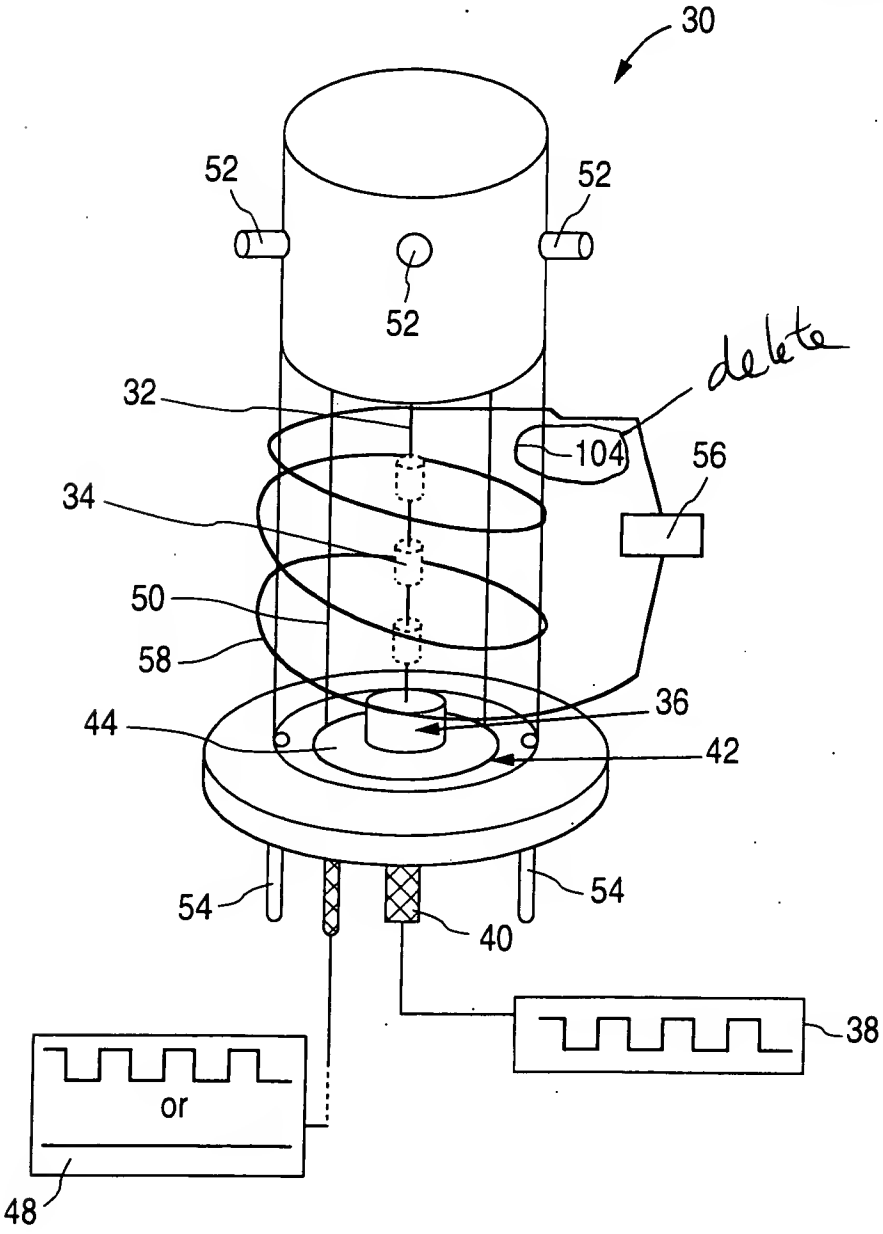


Figure 3